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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,451	10/21/2003	Michael C. Sherman	4002-3274	3728

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WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER

SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/690,451	Applicant(s) SHERMAN ET AL.	
	Examiner James L. Swiger	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 40-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☒ Claim(s) 33 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/4/06 ; 9/6/05 ; 11/14/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Invention I claims 1-39 in the reply filed on 5/22/2006 is acknowledged. The traversal is on the ground(s) that "searching and examining the entire application can be made without serious burden." This is not found persuasive because of the reasons disclosed in the election restriction dated 4/17/2006 regarding the apparatus and method.

The requirement is still deemed proper and is therefore made FINAL.

Claims 40-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/22/2006.

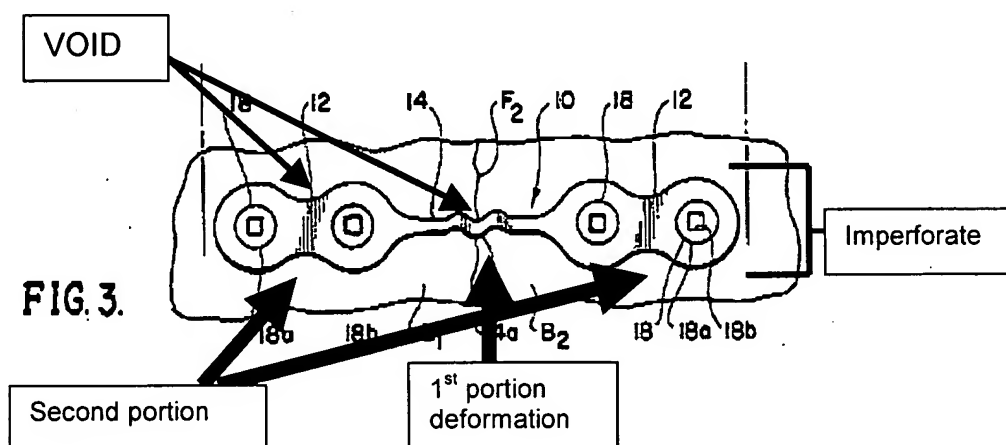
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-19, 22-23 and 38-39 rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan (US Patent 4,905,679) in view of Alexander et al. (US Patent No. 4,512,038). Morgan disclose an orthopedic device (Fig. 3) for the fixation of two or more bone portions, an elongate member (14) that, as shown in Fig. 3, has bends that are capable of allowing the bone portions to at least move with translational movement

with respect to one or another, and a fastener (18) that secures at least one of the elongate member to one or more bone portions. Morgan also discloses an elongate member that is composed of a biocompatible material (Col. 3, lines 65-66) that may be titanium. The device of Morgan may also be considered a plate, as it has a substantial plane against the bone's surface (see Fig. 2 and 3), has a plurality of voids (see Fig. 3 below).



In addition to voids, the plate of Morgan allows deformation in the first portion (Compare figs 1 and 3), and resisting deformation in the second. Further the device of Morgan is capable of performing the method of fixedly attaching the device to two or more bone portions (see claim 2, column 8).

Morgan '679 discloses the claimed invention except for a reinforcing component that is made of a biodegradable material that may be engaged on an elongate member to inhibit translational movement. Alexander et al. disclose a reinforcing material (see Fig. 3), that is capable of being placed on the device of Morgan as reinforcement because it has adequate structure (See carbon fibers in Col. 3, lines 29-41) and is biodegradable over time. As it reabsorbs into the body, it would also be capable of transferring more of the translational movement to the elongated member, since its

stronghold on the elongate member would be reduced. Also the rate at which the reinforcing component of Alexander et al. degrades and the amount of mass left after this period would be capable of being performed by Alexander et al. as the rate of absorption may be adjusted (Col. 3, lines 55-61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Morgan having at least a reinforcing element made of a biodegradable material in view of Alexander et al. to better allow the device to gradually translate support to the bone plate or orthopedic device in view of Alexander et al. to better allow the bone portions to heal at their natural rate.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Morgan '679 and Alexander et al. '038 as applied to claim 1 above, and further in view of Justis et al. (US Patent 6,293,949). The combination of Morgan '679 and Alexander et al. '038 disclose the claimed invention except for the elongate member formed of an elastic material. Justis et al. discloses a device that uses a pseudo-elastic shape-memory material (see Col. 3, lines 30-38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Morgan '679 and Alexander et al. '038 having at least a material that is elastic in view of Justis et al. to better arrange the orthopedic device onto the bones.

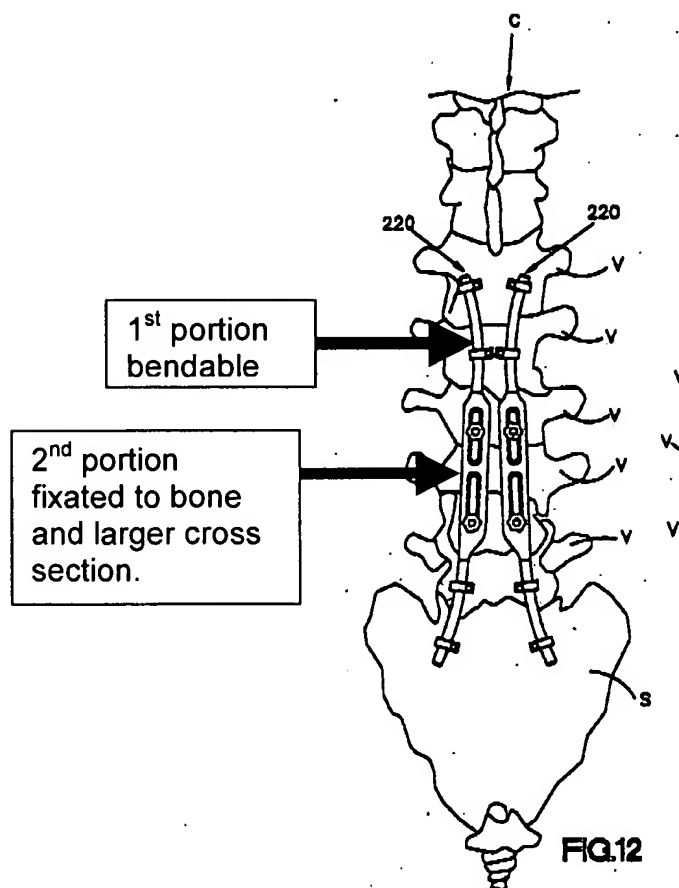
Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Morgan '679 and Alexander et al. '038 as applied to claim 19 above, and further in view of Cohen (US 6,206,882). The combination of Morgan '679 and

Alexander et al. '038 disclose the claimed invention except for a plurality of voids in the center portion that may be deformed and reinforced by the reinforcing material. Cohen teaches voids in the central, deformable area to allow flexibility of the device and to allow it to conform to the shape of the bones needed (See Col. 3 lines 60-67 through Col. 4, lines 1-2. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Morgan '679 and Alexander et al. '038 having at least a plurality of voids in the central region to allow the plate to be more flexible and attach to the reinforcing member in view of Cohen to better use the device.

Claims 24-32 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Morgan '679 and Alexander et al. '038 as applied to claim 1 above, and further in view of Heinig et al. (US Patent 4,887,595). The combination of Morgan '679 and Alexander et al. '038 discloses the claimed invention except for an elongate member that is an orthopedic rod that may be a spinal rod, that has a plurality of voids, and that is capable of being deformed. Heinig et al. discloses a deformable spinal rod (220) that may fit to the spine (see Col 1, lines 55-57), is capable of having reinforcing material onto it, wherein the end is considered imperforate (see drawing below), has a first portion that can be deformed (see drawing below) and a second end that was intended to resist deformation and is adjacent to the first portion (see drawing below) also wherein the second has a larger cross section. These modifications allow for the connections of at least two or more bone portions and reduces stress loading. (see Col. 1 lines 49-69 through Col. 2, lines 1-35). It would have

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been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Morgan '679 and Alexander et al. '038 having at least an elongate member that is an orthopedic rod that may be a spinal rod, that has a plurality of voids, and that is capable of being deformed in view of Heinig et al. to better secure the spinal area in use.



Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Morgan '679 and Alexander et al. '038 and Heinig et al. '595 as applied to claim 24 above, and further in view of Burton (US Patent 4,743,260). The combination of Morgan '679 and Alexander et al. '038 and Heinig et al. '595 disclose the

claimed invention except for an interior lumen having a reinforcing material. Burton discloses a rod with a hollow interior (18a) that may have a reinforcing material inside for support (see Col. 4, lines 21-27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination Morgan '679 and Alexander et al. '038 and Heinig et al. '595 having at least a hollow interior lumen for reinforcing material in view of Burton '260 to better secure and structure the device in use.

Allowable Subject Matter

Claim 33 and 34 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

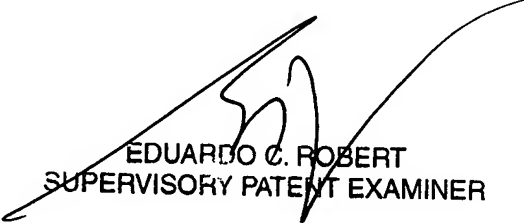
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS 8/2/06

JLS


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER